

**Recombinant DNA Advisory Committee Submission  
BB IND 8559**

**Protocol Number TG4010.03**

**Protocol Title: Randomized Multicenter PHASE II study Evaluating two dosing  
schedules of TG4010 (MVA-MUC1-IL2 ) -in patients with ADENOCARCINOMA OF  
THE PROSTATE**

**Scientific Abstract**

A phase II open label randomized multicenter study comparing two inoculation schedules of  $10^8$  pfu TG4010 (MVA-MUC1-IL2) given by subcutaneous injection, either weekly for six (6) weeks followed by every 3 week schedule (in arm 1) or every three (3) weeks (in arm 2) for twelve weeks. Thereafter, patients qualify according to their response barring related toxicity, therapy can continue until disease progression or clinical plateau. Inclusion criteria include: histologically confirmed, MUC-1 positive cancer, status post-surgical or radiotherapy with rising PSA in the preceding six months; ECOG PS of 0, 1, or 2; adequate hematologic, hepatic and renal function;  $\geq 18$  years old, not HIV+, no other serious concomitant systemic medical disorder. A minimax design is used with enrollment extended to a total of 50 patients if there is one objective response ( $\geq 50\%$  decline in PSA) is confirmed in the initial 30 patients. Assessment criteria include PSA level, overall safety (frequency of adverse events and abnormal laboratory events) and measurement of MUC-1 and MVA -T cell responses.